

Serial No.: 09/844,517
Filed: 04/27/2001
Group Art Unit: 1648



EXPRESS MAIL CERTIFICATE

Date 1/12/04 Label No. EL9839513504S
I hereby certify that, on the date indicated above, this paper or fee
was deposited with the U.S. Postal Service & that it was addressed
for delivery to the Commissioner for Patents, PO Box 1450,
Alexandria, VA 22313-1450 by "Express Mail Post Office to
Addressee" service.
Pat Campbell [Signature]
Name (Print) Signature

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR
CREDIT ANY EXCESS IN THE FEES DUE WITH THIS
DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Customer No.: 29311

Docket No.: 02427/100G772-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Erich HOFFMANN

Serial No.: 09/844,517

Group Art Unit: 1648

Confirmation No.: 9063

Examiner: Myron G. Hill

Filed: April 27, 2001

For: DNA TRANSFECTION SYSTEM FOR THE GENERATION OF
INFECTIOUS INFLUENZA VIRUS

DECLARATION OF ERICH HOFFMANN UNDER 37 C.F.R. § 1.132
AND IN ACCORDANCE WITH IN RE KATZ

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Erich HOFFMANN, do hereby declare and state as follows:

{W:\02427\100G772-000\00090121.DOC *02427100G772-000* }

Serial N .: 09/844,517

Filed: 04/27/2001

Gr up Art Unit: 1648

1. I am a citizen of Germany and am more than twenty-one years of age.
 2. I am the sole inventor of the subject matter described and presently claimed in the above-identified patent application.
 3. I have read and am familiar with the instant application as it was filed in the U.S. Patent and Trademark Office (the "USPTO"), the pending claims of that application as amended on February 10, 2003, and the Office Action mailed by the USPTO on August 12, 2003 in connection with that application.
 4. Gabriele Neumann, Gerd Hobom, Robert G. Webster, Yoshihiro Kawaoka, and myself are also co-authors of the article entitled "'Ambisense' Approach for the Generation of Influenza A Virus: vRNA and mRNA Synthesis from One Template" published in *Virology*, Volume 267, Issue 2, pp. 310-317 (hereinafter "Hoffmann *et al.*"). Upon information and belief, this article was published on February 15, 2000, *i.e.*, less than one year prior to the filing date of the present application.
 5. I understand that the publication listed in ¶4 (Hoffmann *et al.*) was relied upon in the above-mentioned Office Action to reject claims 15-32 and 39 of the application under 35 U.S.C. § 102(a). The present declaration is submitted to describe the contribution of the authors of the publication listed in ¶4.
 6. Co-authors Gabriele Neumann, Gerd Hobom, Robert G. Webster, and Yoshihiro Kawaoka provided financial support, encouragement, supplied reagents, and were named as co-authors of the publication because of those contributions. They did not contribute to the design of a pol I-pol II plasmid for expression of an influenza polymerase protein PB1 (see Hoffmann *et al.*)
- {W:\02427\100G772-000\00090121.DOC *02427100G772-000* }

Serial No.: 09/844,517

Filed: 04/27/2001

Group Art Unit: 1648

al., Figure 1), or to showing that such a PB1 protein was capable of reconstituting the replication and transcription of viral RNA (see Hoffmann *et al.*, Figure 2).

7. Co-author Robert G. Webster was the Principal Investigator and the head of the laboratory where I worked as a Postdoctoral Fellow at the Department of Virology and Molecular Biology at St. Jude Children's Research Hospital, Memphis, Tennessee. Robert G. Webster provided financial support, encouragement, and the influenza A virus A/WSN/33.

8. Co-author Gabriele Neumann was a Postdoctoral Fellow and co-author Yoshihiro Kawaoka was a Professor at the Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison, Madison, Wisconsin who provided me with the plasmids pPolI-WSN-PB1, pPolI-WSN-PB2, pPolI-WSN-PA, pPolI-WSN-NP, pPolI-WSN-HA, pPolI-WSN-NA, pCAGGS-WNA15, and pEWSNHA (see Hoffmann *et al.*, Table 1; compare to Neumann *et al.*, Proc. Natl. Acad. Sci. USA, 1999, 96:9345-50). In addition, I visited the Kawaoka laboratory for two weeks in July 1999 to perform the multiplasmid transfection reported in Table 1 using the pol I-pol II plasmids I prepared myself in my laboratory in Memphis. Dr. Neumann demonstrated the multiplasmid transfection system described in Neumann *et al.*, Proc. Natl. Acad. Sci. USA, 1999, 96:9345-50. Prior to visiting the Kawaoka laboratory, I had already established sufficient transfection efficiency in a model system (see Hoffmann *et al.*, Figure 2) using an alternative transfection system.

9. Co-author Gerd Hobom was a Professor at Institut für Mikro- und Molekularbiologie, Giessen, Germany who provided me with plasmid pHH21 (see page 316, first column, of Hoffmann *et al.*).


{W:\02427\100G772-000\00090121.DOC *02427100G772-000* }

Serial No.: 09/844,517
Filed: 04/27/2001
Group Art Unit: 1648

10. The generation of a pol I-pol II plasmid capable of expressing the PB1 viral gene and demonstrating that this construct expressed effective levels of PB1, as shown in Figure 2 of Hoffmann *et al.*, was my sole invention. Gabriele Neumann, Gerd Hobom, Robert G. Webster, and Yoshihiro Kawaoka did not, therefore contribute to the conception of any of the presently claimed subject matter of the instant application.

11. I further declare that all statements herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application or any patent issuing thereon.

Dated: Jan 12 - 2004


Erich Hoffmann, Ph.D.

{W:\02427\100G772-000\00090121.DOC *02427100G772-000* }

4

Docket No.: 02427/100G772-US1